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PRINCIPAL INVESTIGATOR: Pathik D. Wadhwa, M.D., Ph.D.

CONTRACTING ORGANIZATION: The University of Kentucky
Lexington, Kentucky 40506

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NOTE:

This project was approved and funded for a three-year period from October 1, 1999 till September 30, 2002. The project's Principal Investigator, Pathik D. Wadhwa, M.D., Ph.D., left the University of Kentucky College of Medicine (applicant organization) to accept a new faculty position at the University of California, Irvine, College of Medicine from September 1, 2000 onwards. The University of Kentucky has formally agreed to relinquish the grant award, and the PI is in the process of submitting the necessary paperwork through his new university to seek approval to transfer the award there. Thus, this report covers work performed at the University of Kentucky for the period from 10/1/99 till 8/31/00. Moreover, the PI apologizes for the delay in submitting this progress report – the paperwork for the submission was sent to the PI's old university and did not get here in time for a timely submission.

INTRODUCTION:

The broad objective of the present program of research is to study physiological processes that may mediate the links between psychological states and cancer. Specifically, the present study is designed to conduct an investigation of the cross-sectional associations between indices of stress reactivity and psychological coping styles in women with breast cancer and matched healthy controls. The aims of the project are: (1) To quantify parameters of biological reactivity to a behavioral stress paradigm in women with and without breast cancer; (2) To examine (a) group differences between women with and without breast cancer in biological stress reactivity, and (b) the effects of menopause and familial risk on biological stress reactivity and emotional expression; and (3) To develop the methodology and obtain preliminary data which could justify subsequent, prospective research with high-risk populations.

BODY:

The approved statement of work contains the following tasks to be accomplished in the first year of this project:

- (1) Pilot testing of procedures in the first two months of funding on 12 subjects.
- (2) Recruitment and assessment of approximately 5- 6 subjects per month.
- (3) Construction of a relational database.
- (4) Hormone assays (in batches every 6 months)

Pilot testing has been completed, and manipulation checks have been performed to ensure the adequacy of procedures related to all aspects of the protocol, and especially of the behavioral stress paradigm in eliciting significant SAM and HPA responses and reactivity.

Recruitment and assessment of subjects has been proceeding smoothly. 48 subjects have completed physiological assessments related to stress and coping styles.

A relational database has been constructed that comprises four categories of data: clinical, sociodemographic, psychosocial, and physiological. With the exception of hormonal data, all data collected thus far has been entered continuously into the relational database. A reliability check on a randomly-selected portion (10%) of the data was performed in July 2000 to assure accuracy in transcription and data entry.

Biosamples have been collected and frozen at -70 degrees C and have been transported successfully to the PI's laboratory at the University of California. The first batch of assays will be run after the approval to transfer the project has been obtained and the necessary IRB approvals have been obtained.

KEY RESEARCH ACCOMPLISHMENTS:

The study protocol has been set up successfully and data collection is on-going. The first preliminary analyses are scheduled to be performed 18 months after the start of the project. Hence, there are no specific accomplishments to report at this relatively early stage of the project.

REPORTABLE OUTCOMES:

As mentioned earlier, data collection is on-going, and there are no reportable outcomes at this stage of the project.

CONCLUSIONS:

There have been no problems associated with the implementation of this project so far. The immediate task at hand is to now obtain approval to move the project to the University of California and to then continue and complete data collection and analyses. There is a large clinical population available at the University of California to continue this project (several-fold larger, in fact, than the population at the University of Kentucky), the PI has more-than-adequate space and laboratory facilities, and is confident that there will be no difficulty with continuing and completing the project in a timely and complete fashion.

REFERENCES: none

APPENDICES: none